monohydrate for inhalation (200M) and lactose monohydrate (5 μm) are added in 31 and 30 layers, respectively (tolerance:±6 layers).

The ingredients sieved in are then mixed together (mixing at 900 rpm).

1.2: Final Mixture

To prepare the final mixture, 32.87 kg of the excipient mixture (1.1) and 0.13 kg of micronised tiotropium bromide monohydrate are used. The content of active substance in the resulting 33.0 kg of inhalable powder is 0.4%.

About 1.1 to 1.7 kg of excipient mixture (1.1) are added to a suitable mixing container through a suitable granulating sieve with a mesh size of 0.5 mm. Then alternate layers of tiotropium bromide monohydrate in batches of about 0.003 kg and excipient mixture (1.1) in batches of 0.6 to 0.8 kg are sieved in. The excipient mixture and the active substance are added in 46 or 45 layers, respectively (tolerance:±9 layers).

The ingredients sieved in are then mixed together (mixing at 900 rpm). The final mixture is passed through a granulating sieve twice more and then mixed (mixing at 900 rpm).

EXAMPLE 2

Inhalation capsules (inhalettes) having the following composition were produced using the mixture obtained according to Example 1:

tiotropium bromide monohydrate:	0.0225 mg
lactose monohydrate (200 M):	5.2025 mg
lactose monohydrate (5 μm):	0.2750 mg
hard gelatine capsule:	49.0 mg
Total:	54.5 mg

EXAMPLE 3:

Inhalation capsules having the composition:

tiotropium bromide monohydrate:	0.0225 mg
lactose monohydrate (200 M):	4.9275 mg
lactose monohydrate (5 μm):	0.5500 mg
hard gelatine capsule:	49.0 mg
Total:	54.5 mg

The inhalable powder needed to prepare the capsules was obtained analogously to Example 1.

Example 4:

Inhalation capsules having the composition:

tiotropium bromide monohydrate:	0.0225 mg
lactose monohydrate (200 M):	5.2025 mg
lactose monohydrate (5 μm):	0.2750 mg
polyethylene capsule:	100.0 mg
Total:	105.50 mg

The inhalable powder needed to prepare the capsules was obtained analogously to Example 1.

For the purposes of the present invention the mean particle size denotes the value in μm at which 50% of the particles from the volume distribution have a particle size which is smaller than or equal to the value specified. Laser diffraction/dry dispersion is used as the method of measurement for determining the total distribution of the particle size distribution.

We claim:

1. An inhalable powder comprising 0.04 to 0.8% of tiotropium in admixture with a physiologically acceptable excipient, wherein the excipient consists of a mixture of coarser excipient with an average particle size of 15 to 80 μm and finer excipient with an average particle size of 1 to 9 μm, the proportion of the finer excipient constituting 1 to 20% of the total amount of excipient, wherein the inhalable proportion of active substance is released reproducibly in low variability amounts when administered to a patent.

2. An inhalable powder according to claim **1**, wherein the tiotropium is present in the form of the chloride, bromide, iodide, methanesulphonate, para-toluenesulphonate or methyl sulphate thereof.

3. An inhalable powder comprising between 0.048 and 0.96% of tiotropium bromide in admixture with a physiologically acceptable excipient, wherein the excipient consists of a mixture of coarser excipient with an average particle size of 15 to 80 μm and finer excipient with an average particle size of 1 to 9 μm, the proportion of the finer excipient constituting 1 to 20% of the total amount of excipient, wherein the inhalable proportion of active substance is released reproducibly in low variability amounts when administered to a patent.

4. An inhalable powder comprising between 0.05 and 1% of tiotropium bromide monohydrate in admixture with a physiologically acceptable excipient, wherein the excipient consists of a mixture of coarser excipient with an average particle size of 15 to 80 μm and finer excipient with an average particle size of 1 to 9 μm, the proportion of the finer excipient constituting 1 to 20% of the total amount of excipient, wherein the inhalable proportion of active substance is released reproducibly in low variability amounts when administered to a patent.

5. An inhalable powder according to one of claims **1**, **2**, **3** or **4**, wherein the excipient consists of a mixture of coarser excipient with an average particle size of 17 to 50 μm and finer excipient with an average particle size of 2 to 8 μm.

6. An inhalable powder according to one of claims **1**, **2**, **3** or **4**, wherein the proportion of finer excipient in the total amount of excipient is 3 to 15%.

7. An inhalable powder according to one of claims **1**, **2**, **3** or **4**, wherein the tiotropium used has an average particle size of 0.5 to 10 μm.

8. An inhalable powder according to one of claims **1**, **2**, **3** or **4**, wherein one or more monosaccharides, disaccharides, oligo- or polysaccharides, polyalcohols, salts thereof, or mixtures thereof are used as the excipients.

9. An inhalable powder according to claim **8**, wherein glucose, arabinose, lactose, saccharose, maltose, dextrane, sorbitol, mannitol, xylitol, sodium chloride, calcium carbonate or mixtures thereof are used as the excipients.

10. An inhalable powder according to claim **9**, wherein glucose or lactose or mixtures thereof are used as the excipients.

11. A process for preparing an inhalable powder according to one of claims **1** to **4**, comprising: (a) mixing coarser excipient fractions with finer excipient fractions to obtain an excipient mixture, and (b) mixing the excipient mixture thus obtained with the tiotropium.

12. A method of treating a disease that is responsive to the administration of tiotropium, comprising administering to a